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October 20, 2000

Secretary Donna Shalala  
U.S. Dept. of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Shalala:

The Food and Drug Administration may shortly propose changes to the way hearing aids are sold that could put me out of business and impede access to hearing care services for millions of our nation's seniors.

I am a state-licensed hearing instrument specialist. For over 7 years, I have provided hearing health care services to hundreds of our state's hearing-impaired. Presently, all three members of the hearing health care delivery team (hearing aid specialists, audiologists and physicians) are recognized as qualified entry points into the hearing health care delivery system. The rule FDA is advocating would allow audiologist--without any justification--to install themselves as the sole entry point into hearing health care by allowing states to require tests that only audiologists conduct prior to purchase of a hearing aid.

Allowing audiologist an exclusive role in the hearing aid delivery system, without unqualified medical data evidencing that such role is necessary for public health reasons, would severely undermine public health and safety and would increase costs to the hearing impaired.

Please write to the Secretary of Health and urge that this FDA proposed hearing aid rule be withdrawn.

I look forward to your response and would appreciate a copy of any letter you send on my behalf.

Sincerely yours,

93N 0372

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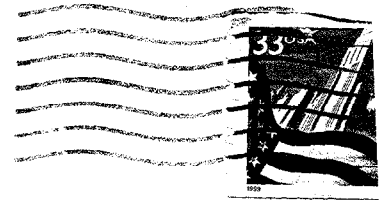


**James V. DeSanto, HIS**

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U.S. Dept of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

